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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,541	07/25/2003	Bjorn T. Langeland	3657-1014	1166
466	7590	10/20/2004	EXAMINER	
YOUNG & THOMPSON 745 SOUTH 23RD STREET 2ND FLOOR ARLINGTON, VA 22202			TATE, CHRISTOPHER ROBIN	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/626,541	<b>Applicant(s)</b> LANGELAND, BJORN T.	
	<b>Examiner</b> Christopher R. Tate	<b>Art Unit</b> 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 1654

### **DETAILED ACTION**

The preliminary amendment filed July 25, 2003 has been received and entered.

Claims 1-11 are presented for examination on the merits.

#### ***Claim Objections***

The claims are objected to because of the following informalities:

The claims contain several typos including in claim 1 - "senticous" (apparently should be --senticosus--); in claim 3 - a period symbol appears at line 10; in claim 10 - unmatched parenthesis symbol (e.g., at step c).

Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 5 and 11 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered vague and indefinite because it fails to recite any operative amounts of the claimed herbal ingredients. Therefore, it is unclear if each of these recited ingredients is an active agent within the composition, if it is merely some type of inert agent, and/or if it is present in very small amounts representing perhaps a contaminant or residue. The claimed herbal ingredients are each deemed to be essential elements of the invention and, as such, they should be clearly defined (e.g., functionally) in the claim language itself. Accordingly, it is suggested that the term "comprising" (line 1) be expanded to recite --to promote alcohol and acetaldehyde degradation comprising effective amounts of-- or, alternatively, that the limitations recited in claim 3 be appropriately incorporated into claim 1 to clarify this ambiguity (however, please note that claim 3 also needs clarification as discussed below).

In claim 1, the metes and bounds of the terms "caffeine" and "Guarana caffeine" (line 1) are not clearly delineated, each from the other - i.e., caffeine is a chemical compound regardless of its source. Accordingly, it is unclear if the composition comprises caffeine plus addition amounts of caffeine (from Guarana), caffeine plus Guarana extract that contains caffeine, or something else.

Art Unit: 1654

Claims 2 and 4 are rendered vague and indefinite by the respective phrases "composition of claim 1 wherein an analgesic is present" and "composition of claim 1 wherein green tea is present" because this would make it seem that the agents are already present in the composition of claim 1. It is suggested that claims 2 and 4 be amended so as to recite --composition of claim 1 wherein ... is added-- or --composition of claim 1, further comprising ....--.

Claims 3 and 10 are rendered vague and indefinite by the linking terms "preferably", "i.e.", and "e.g.". A broad range or limitation followed by linking terms (for example, preferably, maybe, for example, for instance, especially, that is) and a narrow range or limitation within the broad range or limitation is considered indefinite since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired (see MPEP 2173.05(c) for additional information).

Claims 3, 10, and 11 are rendered vague and indefinite by parenthetical phrases recited therein (other than the parenthetical phrases in claim 3 concerning percentages/dry weights). The use of parentheses encompassing terminology (e.g., listings therein reciting ingredients and/or undesirable effects) in the claims is indefinite because it is unclear if what is stated in parentheses is a further limitation or simply alternative meaning.

Claim 3 is also rendered vague and indefinite because it is more than one sentence long which is improper and indefinite (e.g., it is unclear if the limitations recited after the period symbol at line 10 are actual limitations of claim 3).

Claim 3 is further rendered vague and indefinite by the phrase "the ingredients not comprised by claims 1-2" because "the ingredients" lack antecedent basis and it is unclear as to what this phrase limitation is actually defining.

Art Unit: 1654

Claims 5 and 11 provide for the use of, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 6 is rendered vague and indefinite by the phrase "where the composition may be formulated" because it is unclear by the wording "may be" if the composition is or is not formulated as such. It is suggested that the phrase "may be" be omitted and replaced with --is--.

Claims 7, 8 and 10 recite the limitation "aqueous product according to claim 1" in line 1 of each. There is insufficient antecedent basis for this limitation in these claims (i.e., the composition of claim 1 is not defined as being an aqueous product).

Claim 9 recites the limitation "pharmaceutical product according to claim 1" in line 1. There is insufficient antecedent basis for this limitation in the claim (i.e., the composition of claim 1 is not defined as being a pharmaceutical product).

Claim 10 recites the limitation "the dry components" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 10 is also rendered vague and indefinite by the step c) phrase "adding the ingredients ... and optionally ginkgo biloba" because in claim 1 (from which claim 10 depends), ginkgo biloba is not an optional ingredient, it is a required ingredient. Accordingly, this step limitation is outside a method of preparing the composition according to claim 1.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, and 4-9, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bell et al. (US 2003/0138520) with evidence provided by Park et al. (US 2003/0026858) and Sawaguchi (JP 62292725 - JPAB Abstract).

Bell et al. teaches compositions including compositions within carrier bodies (thus read upon pharmaceutical compositions) which beneficially contain one or more medicinal herbs/compounds/plant materials such as caffeine, *Guarana*, matte (aka *Yerba mate*), Siberian ginseng (aka *Eleutherococcus senticosus*), *Panax ginseng*, ginger, licorice (aka *Glycyrrhiza glabra*), Ginkgo biloba, and green tea; as well as water (i.e., aqueous product) therein. In addition, Bell et al. beneficially teaches that a prebiotic can also be incorporated as an active ingredient therein whereby the prebiotic contains fructose (see entire document including, e.g., paragraphs [0006], [0007], [0013], [0015], [0016], [0018], [0020], [0031], [0033], and claims 5, 7-8).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare a composition (such as disclosed by Bell et al.) comprising various herbal and non-herbal ingredients advantageously taught by Bell et al. - including those instantly claimed - for their art-recognized medicinal effects, based upon the beneficial teaching provided by the cited reference, as discussed above. The adjustment of particular conventional

Art Unit: 1654

working conditions (e.g., using a particular combination of medicinal herbal agents from among those beneficially taught by the cited reference, determining a result-effective amount of such herbal ingredients, including a fructose-containing prebiotic and/or further including fructose as a conventional commonly employed carrier therein) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. Please note that although the Bell et al. reference does not expressly teach that an analgesic is present therein (as instantly claimed), Panax ginseng and licorice are each well known in the art to have analgesic activity - as evidenced by Park et al. and Sawaguchi, respectively, (see, e.g., Park - paragraph [0002] and Sawaguchi - JPAB abstract). Accordingly, analgesic activity would intrinsically be present in the reference compositions that contain licorice and/or ginseng.

Thus, the invention as a whole is prima facie obvious over the reference, especially in the absence of evidence to the contrary.

### **Conclusion**

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.



Art Unit: 1654

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Christopher R. Tate  
Primary Examiner  
Art Unit 1654